IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, et al., *ex rel.* PEGGY RYAN,	:	
	:	**CIVIL ACTION**
Plaintiffs,	:	
	:	**NO.: 05-cv-3450**
v.	:	
ENDO PHARMACEUTICALS INC.,	:	
Defendant.	:	

UNITED STATES OF AMERICA, et al., *ex rel.* MAX H. WEATHERSBY, et al.,	:	
	:	**CIVIL ACTION**
Plaintiffs,	:	
	:	**NO.: 10-cv-2039**
v.	:	
ENDO PHARMACEUTICALS INC., et al.,	:	
Defendants.	:	

UNITED STATES OF AMERICA, *ex rel.* GURSHEEL S. DHILLON,	:	
	:	**CIVIL ACTION**
Plaintiff,	:	
	:	**NO.: 11-cv-7767**
v.	:	
ENDO PHARMACEUTICALS,	:	
Defendant.	:	

UNITED STATES' MEMORANDUM ON THE ELIGIBIILTY OF
RELATORS FOR A SHARE OF FEDERAL SETTLEMENT PROCEEDS

On February 21, 2014, the parties to these *qui tam* actions entered into a settlement under which defendants Endo Health Solutions, Inc. and its subsidiary Endo Pharmaceuticals Inc. ("Endo") paid approximately $171.9 million to resolve alleged False Claims Act ("FCA") violations arising out of Endo's promotion of the drug Lidoderm for uses such as low back pain and chronic pain that were off-label and not covered by federal and State health care programs. Lidoderm is an adhesive patch that is applied to the skin and is approved only for the treatment of pain related to post-herpetic neuralgia ("PHN"), a complication that sometimes accompanies shingles. Of the settlement proceeds, Endo paid: (1) $137,534,005 plus interest to the federal government; and (2) $35,382,961 to participating States and the District of Columbia. In a related criminal action in the Northern District of New York, Endo also entered into a Deferred Prosecution Agreement with the United States and paid criminal fines and forfeiture totaling approximately $20.8 million.

At the time of the settlement, the three above-captioned actions were pending in this Court. The Ryan action was filed in 2005; the Weathersby action, in 2010; and the Dhillon action, in 2011. All three actions generally allege that Endo promoted Lidoderm for uses that are not approved by the Food and Drug Administration and indications that were not medically accepted, thus causing false claims to be submitted to federal health care programs. All relators have agreed that the February 2014 civil settlement of the off-label marketing allegations was fair, adequate, and reasonable. Specifically reserved at the time of the settlement was the issue of relators' entitlement to a share of the federal proceeds of the FCA settlement.

In this opening brief, to which relators will respond, the United States sets forth the relevant legal framework for applying the FCA's first-to-file provision, 31 U.S.C. 3730(b)(5).

The United States also addresses the related question of the applicability of Federal Rule of Civil Procedure 9(b) to FCA complaints. Finally, the United States includes a discussion of the FCA's public disclosure provision, which relators have previously indicated they may raise.

I. THE FALSE CLAIMS ACT

The False Claims Act, 31 U.S.C. 3729 et seq., establishes civil liability for, among other things, knowingly submitting or causing to be submitted false claims to the United States. An FCA action may be brought by either the Attorney General or a private person, known as a relator, on behalf of the government. 31 U.S.C. 3730(a); 31 U.S.C. 3730(b)(1). Actions by relators are known as "*qui tams.*" If a relator brings a *qui tam* action, the complaint is initially filed under seal and served upon the government, and the government may elect to intervene and proceed with the action. 31 U.S.C. 3730(b)(3). If the government declines to intervene in a *qui tam* action, the relator "shall have the right to conduct the action.'" 31 U.S.C. 3730(c)(3).[1] If a *qui tam* action results in a recovery, a proper relator is entitled to a "share" of the recovery in the range set forth in the statute. 31 U.S.C. 3730(d). Such a relator is also entitled to seek attorneys' fees, costs, and expenses from the defendant. Id.

Of particular relevance to this case, the FCA includes a "first-to-file" bar, 31 U.S.C. § 3730(b)(5), which states that, "[w]hen a person brings [a *qui tam* action], no person other than the Government may intervene or bring a related action based on the facts underlying the

[1] For example, in these Lidoderm cases against Endo, although the United States intervened in and settled the allegations relating to off-label promotion, the United States declined to intervene in certain separate claims asserted in the Weathersby complaints against Endo relating to alleged kickbacks, pricing violations, and retaliation. Those claims were not resolved as part of the settlement and remain pending. The Weathersby relators are free to continue to pursue those claims if they choose to do so and may seek a share of any recovery obtained relating to those claims.

pending action." That provision precludes a second *qui tam* suit from going forward if, at the time the complaint in the second action is filed, an earlier *qui tam* suit, based on the same essential elements of fraud, is already pending in court.

II. THE *QUI TAM* COMPLAINTS

Peggy Ryan worked as an Endo sales representative at all relevant times. On July 5, 2005, she filed a complaint under the *qui tam* provisions of the FCA; she amended it in 2009 before any other relator filed a complaint. Her complaints alleged that Endo engaged in off-label promotion of Lidoderm, causing false reimbursement claims to be submitted to Medicaid and Medicare. Specifically, she alleged that Endo: (a) instructed sales representatives to promote the drug for off-label uses such as low back and other pain; (b) did so, in part, by creating Endo-funded or Endo-prepared articles and studies that appeared to be the product of neutral third parties and that touted Lidoderm's effectiveness for off-label uses; (c) did not seek FDA approval for off-label uses, because the company wanted to maintain Lidoderm's "orphan drug" FDA status as a drug treating a condition (PHN) affecting fewer than 200,000 persons, a status that afforded special tax incentives and exclusivity; and (d) paid unspecified kickbacks to induce physicians to prescribe Lidoderm.

Over several years, beginning in 2005, Ms. Ryan served as a confidential source in the United States' covert criminal investigation of Endo. In January 2007, the Office of Inspector General of the United States Department of Health and Human Services ("HHS-OIG") subpoenaed Endo to produce Lidoderm marketing-related documents. See Exhibit "A" hereto (HHS-OIG subpoena). At the same time, Endo issued a press release acknowledging its receipt of the subpoena, which was also reported in the news media. See . Exhibit "B" hereto (Endo

Press Release). In SEC filings in 2007 and later years, Endo disclosed its receipt of the subpoena. See, e.g., Exhibit "C" hereto (Endo SEC filing).

In May 2010, Max Weathersby, also an Endo sales representative, filed his complaint on behalf of the United States and various States and the District of Columbia, which he amended several times. In these complaints, he acknowledged that Endo "since at least January 2007[] has been under investigation by the Federal Government for issues relating to potential off-label promotion of . . . Lidoderm." The Weathersby complaints identified specific tools that Endo allegedly used to further the off-label promotion scheme, such as: (1) call lists and practice guidelines; and (2) quotas and bonuses to sales representatives to spur off-label sales. The complaints also averred that: (1) Endo suppressed studies showing a lack of efficacy, or negative results, for off-label Lidoderm uses; and (2) Endo provided free samples and other kickbacks in order to induce referrals of Lidoderm. The last amended complaint added a second relator, MK Litigation Partnership, and a retaliation claim for wrongful termination.

In February 2011, physician Gursheel Dhillon filed a complaint alleging that Endo engaged in Lidoderm off-label promotion. (After the complaint was filed in the Middle District of Tennessee, the action was transferred to this District.) Like the Weathersby complaints, Dr. Dhillon's complaint acknowledged an ongoing federal investigation into Lidoderm off-label marketing and, further, cited to related: (1) posts on an internet website discussion board; and (2) Endo SEC filings. He averred that, beyond this public information, his knowledge was based on statements made in his presence by Endo speakers and sales representatives. He also alleged that Endo paid bonuses to its sales representatives to spur Lidoderm off-label marketing.

In 2010 as to Weathersby and Ryan, and in 2012 as to Dhillon, the United States disclosed the existence of all of the sealed cases to each of the relators, after obtaining appropriate court orders permitting it to make such discloses. By 2012, the United States had notified all relators that the existence of overlapping cases potentially implicated the first-to-file bar of the FCA. All relators have thus known about the pendency of all of the actions for over two years.

III. LEGAL ANALYSIS

A. The First-To-File Provision Employs An "Essential Elements" Test

The FCA's Section 3730(b)(5) first-to-file bar creates "an incentive for relators with valuable information to file – and file quickly." In re: Natural Gas Royalties Qui Tam Litig. (CO2 Appeals), 566 F.3d 956, 961 (10th Cir. 2009); accord Campbell v. Redding Med. Ctr., 421 F.3d 817, 821 (9th Cir. 2005) ("the first-to-file bar . . . encourages prompt disclosure of fraud by creating a race to the courthouse among those with knowledge of fraud"); see also, e.g., Wisconsin v. Amgen, Inc., 516 F.3d 530, 532 (7th Cir. 2008) ("Congress didn't want these bounty hunters piling into the first-filed suit and fighting over the division of the spoils, or, to the same end, bringing separate such suits"); Grynberg v. Koch Gateway Pipeline Co., 390 F.3d 1276, 1279 (10th Cir. 2004) ("original qui tam relators would be less likely to act on the government's behalf if they had to share in their recovery with third parties who do no more than tack on additional factual allegations to the same essential claim"). "The first-to-file bar thus functions both to eliminate parasitic plaintiffs who piggyback off the claims of a prior relator, and to encourage legitimate relators to file quickly by protecting the spoils of the first to bring a claim." In re: Natural Gas Royalties Qui Tam Litig., 566 F.3d at 961.

The first-to-file bar is also based upon the policy that "duplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." United States ex rel. LaCorte v. SmithKline Beecham Clinical Laboratories, Inc., 149 F.3d 227, 234 (3d Cir. 1998). For a later-filed *qui tam* action to be barred, its allegations need not be identical to those in the first-filed case. Rather, as the Third Circuit has held, "if a later allegation states all the essential facts of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim, even if that claim incorporates somewhat different details." Id. at 232-33. Other courts of appeals have adopted a similar test. See United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 32 (1st Cir. 2009); Walburn v. Lockheed Martin Corp., 431 F.3d 966, 971 (6th Cir. 2005); United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1187-89 (9th Cir. 2001). A later-filed action is barred even when "the Court does not doubt [the later relator's] motives or that [she] has additional details as to the scope of defendants' allegedly fraudulent practices which may aid [the first relator] as she pursues her claims against the defendants on behalf of the government." Palladino ex rel. United States v. VNA of Southern New Jersey, Inc., 68 F. Supp. 2d 455, 478 (D.N.J. 1999).

When conducting a first-to-file analysis, a court compares the complaints filed in the related actions to see whether the later-filed actions have the same essential elements as the first-filed one. LaCorte, 149 F.3d at 234-35 n. 6. Thus, in LaCorte, the Third Circuit compared earlier-filed, general claims with later-filed, but more-specific claims and held that, notwithstanding the generality of the earlier claims, the "material elements" of the claims were the same. Consequently, the later-filed claims were barred. Id. at 235-237. For example, the

essential facts of one earlier-filed claim were "merely that [the defendant] tested and billed for blood samples that had not been ordered by any physician." That allegation barred later relators' more-specific allegations that the defendant: (1) during its employees' "phony screening programs," drew blood and urine specimens from nursing home patients without informing the patients' physicians; (2) then performed unauthorized CBC, hematology, urinalysis, and blood chemistry tests on those samples, charging the government for those services; and (3) billed the government for drawing and transporting the specimens. Id. at 236. Comparison of the complaints at a "sufficiently high level of generality" is thus all that is required. United States ex rel. Folliard v. Synnex Corp., 798 F. Supp. 2d 66, 72 (D.D.C. 2011) (citation omitted).

B. The Role Of Rule 9(b) In The First-To-File Analysis

Courts have consistently held that a first-filed complaint may not operate as a bar to later-filed complaints, however, if the first-filed complaint provides inadequate notice of the fraud. But courts are divided over whether the adequacy of notice in the first-filed complaint turns on satisfying Federal Rule of Civil Procedure 9(b) or a lesser standard. The Sixth Circuit has held that a complaint must satisfy Rule 9(b) in order to be given preemptive effect under the first-to-file rule. See Walburn v. Lockheed Martin Corp., 431 F.3d 966, 972-73 (6th Cir. 2005) (reasoning that a complaint that does not pass Rule 9(b) muster "can hardly be said to have given the government notice of the essential facts of a fraudulent scheme"). The D.C. Circuit and the First Circuit, on the other hand, have held that a first-filed complaint "need not meet the heightened standard of Rule 9(b) to bar later complaints" but, instead, "must provide only sufficient notice for the government to initiate an investigation into the allegedly fraudulent practices, should it choose to do so." United States ex rel. Batiste v. SLM Corp., 659 F.3d 1204,

1210 (D.C. Cir. 2011); accord United States ex rel. Heineman-Guta v. Guidant Corp., 718 F.3d 28, 34-36 (1st Cir. 2013). Cf. United States ex rel. Rille v. PricewaterhouseCoopers LLP, 2014 WL 1386953, at *3 (8th Cir. Apr. 10, 2014) (stating, outside of first-to-file context, that Rule 9(b) does not play a part in determining whether a relator is entitled to share of settlement proceeds).

The United States is of the view that the Sixth Circuit's ruling in Walburn is correct.[2] That decision properly balances the competing goals of the FCA and provides a clear and readily applicable standard to determine whether the first-to file bar applies. As the Sixth Circuit reasoned, a complaint that was legally insufficient from its inception under Rule 9(b), because it was vague and pleaded in "broad and conclusory" terms, could not bar a later-filed action under the first-to-file bar. Walburn, 431 F.3d at 972-73. The court explained that "[a] complaint that is insufficient under Rule 9(b) is dismissed precisely because it fails to provide adequate notice to the defendant of the fraud it alleges," and therefore "can hardly be said to have given the government notice of the essential facts of a fraudulent scheme" to "enable the government to uncover related frauds." Id. at 973. Allowing such a deficient complaint to bar a later-filed, related *qui tam* complaint would discourage other relators from coming forward with potentially valuable information about the alleged fraud, contrary to the FCA's "policy of encouraging whistleblowers to notify the government of potential frauds." Id. The benefit of applying a Rule

[2] In none of the cited first-to-file decisions, including Walburn, did a court evaluate under Rule 9(b) or any standard a *first-in-time relator's* entitlement to a share of an executed settlement with a common defendant, let alone where the settlement was executed after a long government investigation and before the defendant had answered the first-in-time relator's complaint. See, e.g., Walburn, 431 F.3d at 969 (affirming dismissal of second-in-time Ohio suit on public disclosure bar grounds, where United States declined to intervene in suit, defendant then moved to dismiss, district court dismissed on first-to-file grounds, and during appeal first-filed suit was dismissed on 9(b) grounds in District of Maryland); LaCorte, 149 F.3d at 230-232 (addressing *second-in-time relators'* non-entitlement to share of United States' settlement with defendant and earlier-filed relators).

9(b) standard instead of a more-amorphous "notice" test is that such a standard, in addition to being measured under a well-established body of law applying Rule 9(b), involves examining only the four corners of a complaint, much like the "essential facts" test undertaken in a first-to-file analysis.

The Third Circuit has not squarely addressed whether the adequacy of notice in the first-filed complaint turns on satisfying Rule 9(b). One of the arguments urged by the later-filed relators in LaCorte, who argued for a narrow "identical facts" test, was that an "essential facts" test would not prevent a relator from filing a broad, non-particular complaint in an effort to preempt later relators' claims. LaCorte, 149 F.3d at 234. In rejecting that concern, the Third Circuit reasoned that Rule 9(b) provided "sufficient deterrence against overly broad allegations." The court further explained that there was no indication that relators in the earlier-filed actions "worded their complaints in excessively general terms for the purpose of thwarting later claims." Id.

Courts have disagreed over whether this discussion in LaCorte supports a Rule 9(b) or a notice standard. Compare, e.g., Walburn, 431 F.3d at 973 (stating, after citing LaCorte, "it is precisely the . . . Rule 9(b) [standard] that deters would-be relators from making 'overly broad allegations' that fail to adequately alert the government to possible fraud"); with, e.g., Heineman-Guta, 718 F.3d at 36-37 & nn. 9, 10 (in rejecting Rule 9(b) standard and citing LaCorte and its progeny for support, stating that "Rule 9(b) is not concerned with providing the government notice sufficient to enable it to launch an investigation" but, rather, "is intended to protect the defendants . . . from frivolous allegations and allow them to prepare an appropriate defense") (quotation marks omitted); United States ex rel. Folliard, 798 F. Supp. 2d 66, 74-76

(D.D.C. 2011) (holding that a first-filed complaint that is not a "sham" complaint and puts the government on sufficient notice bars later relators' claims, which was consistent with LaCorte's reasoning that "the primary purpose of Rule 9(b) dismissal is deterrence [against overly broad allegations], not preclusion"); and Piacentile v. Sanofi Synthelabo, Inc., 2010 WL 5466043, at *4 (D.N.J. Dec. 30, 2010) ("the Third Circuit's concern in LaCorte was with would-be relators bringing unsupported claims merely to preempt others and stake a claim to a *qui tam* windfall"). At least one court in this District has stated that "whether the [earlier-filed] complaint satisfied the pleading requirements of Rule 9(b) is inapposite, because the plain language of [the first-to-file provision] does not include an exception for situations in which a first-filed complaint is pled with insufficient particularity." United States ex rel. Galmines v. Novartis Pharmaceuticals Corp., 2013 WL 2649704, at *10 n.4 (E.D. Pa. June 13, 2013).

Thus, as a threshold matter, a first-filed complaint must meet some minimum pleading requirement – either Rule 9(b) or a notice standard -- in order to bar later-filed complaints. This Court not need reach the question of which of these minimum pleading standards should be adopted, however, if the Court concludes that the relevant first-filed complaint of Ms. Ryan satisfies the more exacting standard of Rule 9(b). If the Court so concludes, then the complaint will also presumably meet a lesser notice standard.

C. The Rule 9(b) Standard In FCA Cases

There is abundant case law on the application of Rule 9(b) to FCA actions. FCA claims must be pleaded with particularly under Rule 9(b). United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 n.9 (3d Cir. 2004). So long as the complaint as a whole identifies the

specifics of a fraudulent scheme and provides an adequate basis (statistical or otherwise) for reasonable inferences that false claims were more than likely submitted to the government because of that scheme, the requirements of Rule 9(b) are satisfied. See United States ex rel. Walker v. R&F Properties of Lake County, Inc., 433 F.3d 1349, 1360 (11th Cir. 2005) (declining to dismiss *qui tam* suit under Rule 9(b) where relator adequately alleged why she believed defendant submitted false claims).

The majority of courts agree that a relator's complaint may be sufficiently detailed and particularized to satisfy Rule 9(b) even if it does not identify specific false claims. See, e.g., Ebeid ex rel. United States v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010) ("We do not embrace [a] . . . categorical approach that would, as a matter of course, require a relator to identify representative examples of false claims to support every allegation"); United States ex rel. Duxbury v. Ortho Biotech Prods., 579 F.3d 13, 29 (1st Cir. 2009) ("[A] relator could satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim.") (quotation marks omitted); United States ex rel. Lusby v. Rolls-Royce Corp., 570 F.3d 849, 854 (7th Cir. 2009) ("We don't think it essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit"); United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009) ("We hold that to plead with particularity the circumstances constituting fraud for a False Claims Act . . . claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted."); United States ex rel. Clausen v. Laboratory Corp. of Am.,

Inc., 290 F.3d 1301, 1311 (11th Cir. 2002) ("[I]f Rule 9(b) is to be adhered to, some indicia of reliability must be given in the complaint to support the allegation of an actual false claim for payment being made to the Government.") (italics omitted).

In the specific context of off-label promotion claims under the FCA, courts have reasoned that the identification of specific false claims is not an absolute prerequisite to satisfying the particularity requirement of Rule 9(b). Indeed, as the First Circuit has stated, in off-label cases, where the alleged false claims were submitted not by the defendant, but instead by a third party, a relator need not allege the details of particular claims, so long as "the complaint as a whole is sufficiently particular to pass muster under the FCA." United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 732 (1st Cir. 2007). Although ultimately dismissing off-label marketing allegations for failure to satisfy the Rule 9(b) pleading requirements, the Rost court explained that sufficiently detailed allegations of an unlawful scheme to promote off-label use of a drug could, in proper circumstances, raise an inference that a defendant's activities caused the submission of false claims to the government. Id. (noting that "it is not irrational to infer that, given the large percentage of children and the elderly who are insured under the federal health programs, some false claims for Genotropin reimbursement were submitted to the government").

In Rost, the First Circuit also confirmed that context matters in assessing the Rule 9(b) sufficiency of pleadings. The court distinguished one case that arose "[i]n the context of a defendant that submits claims directly to government programs" from the false claims at issue in Rost, which were "allegedly submitted by doctors who were allegedly induced and seduced by defendants into prescribing [the at-issue drug] for off-label uses to their patients[.]" Rost, 507 F.3d at 732. The court appeared to suggest that the level of detail required in the identification of

specific false claims should be greater in the former case than the latter because a relator's access to such information would be comparatively greater where the defendant directly submitted the false claims. In short, Rost makes clear that the relevant question is not whether a relator has actually identified specific false claims submitted to the government but whether a relator has provided sufficiently detailed allegations concerning the fraudulent scheme to support a reasonable inference that false claims for reimbursement were submitted. Id. at 733 (noting need for allegations that "strengthen the inference of fraud beyond possibility"). Cf. United States ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 308 (3d Cir. 2011) (affirming dismissal of FCA case under Rule 12(b)(6) "plausibility" grounds without reaching Rule 9(b) and its pleading standard, and noting that "we have never held that a plaintiff must identify a specific claim for payment at the *pleading stage* [as contrasted with the summary judgment stage] of the case to state a claim for relief"); Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658 (3d Cir. 1998) (in non-FCA case, cautioning against overemphasizing Rule 9(b) specificity requirement, and stating that plaintiffs "need not . . . plead the date, place, or time of the fraud, so long as they use an alternative means of injecting precision and some measure of substantiation into their allegations of fraud") (quotation marks omitted).

Courts in this district have reached the same conclusion in FCA off-label cases. See United States ex rel. Bergman v. Abbott Laboratories, 2014 WL 348583, at *11-12 (E.D. Pa. Jan. 30, 2014) (stating "this District has found that a relator does not need to show a specific submitted false claim if the false claims are submitted by a third party [such as a doctor] and not the defendant" and as long as the complaint provides an alternative means of injecting precision and some measure of substantiation into the fraud allegations); United States ex rel. Underwood

v. Genentech, Inc., 720 F. Supp. 2d 671, 677-80 (E.D. Pa. 2010) (holding that relator need not identify a specific false claim at the pleading stage because he described the conduct with sufficient detail and there was "no mystery or ambiguity to these allegations"); United States ex rel. Galmines v. Novartis Pharmaceuticals Corp., 2013 WL 2649704, at *12-13 (E.D. Pa. June 13, 2013) (relator's pleaded details about company's training of personnel and equipping them to off-label market, together with allegation of over a million off-label prescriptions, were sufficiently specific to inform defendant company of conduct "and to make it unlikely that [relator] has commenced this action in bad faith"); United States ex rel. Streck v. Allergan, Inc., 894 F. Supp. 2d 584, 601-02 (E.D. Pa. 2012) (same).

Thus, if the Court concludes that the relevant Ryan complaint satisfies Rule 9(b) and that the later-filed actions contain the same essential elements as Ms. Ryan's case, then she is the eligible relator, the other relators would be barred from receiving a share of the federal settlement proceeds, and those relators would be dismissed as to the settled, off-label claims.

D. The FCA's Public Disclosure Provision

If the Court concludes that Ms. Ryan is the proper relator, then it need not conduct any further inquiry on share eligibility. But in the event that relator eligibility is not resolved on the first-to-file ground, the United States provides a framework for analyzing the applicability of another bar in the FCA, known as the public disclosure bar.

The FCA contains a public disclosure bar that provides that an action will be barred if it is based on a public disclosure of the allegations:

> No Court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing,

> audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4).[3] Thus, the first inquiry under the bar is whether there is a triggering public disclosure. For a disclosure to qualify, it must: (1) be public; and (2) occur in a specified context set forth in the statute. United States ex rel. Mistick PBT v. Housing Authority of the City of Pittsburgh, 186 F.3d 376, 383 (3rd Cir. 1999).

In 2006, before the filings of the Weathersby and Dhillon actions, an article in Business Week discussed Endo's off-label marketing of Lidoderm. The article: (1) reviewed Endo's sales of Lidoderm; (2) noted that over half of Lidoderm prescriptions were for non-FDA-approved uses; (3) described an Endo marketing technique in which Lidoderm sales representatives would give doctors materials on studies that had found Lidoderm to be effective for non-approved uses; and (4) stated that, "for Lidoderm, that includes trials showing the patch is effective on backaches and pain associated with diabetes and osteoarthritis." See Exhibit "D" hereto ("When a Winner Starts to Wane," Business Week, at 82).

In January 2007, the Office of the Inspector General of the U.S. Department of Health and Human Services served Endo with a subpoena commanding production of documents, including documents from 1999-2007 relating to the "off-label use or sales or promotion" of the drug Lidoderm. At that time, there were several news articles about that subpoena and the United States' investigation of Lidoderm off-label marketing. See generally U.S. ex rel. Poteet

[3] In March 2010, the Patient Protection and Affordable Care Act ("PPACA") amended this provision, but the amendments do not retroactively apply to the pre-March 2010 conduct (the only conduct) that was settled in these cases. Graham County Soil and Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 283 n.1 (2010).

v. Bahler Medical, Inc., 619 F.3d 104, 110 (1st Cir. 2010) ("[a]ny transactions and allegations discussed in the news media would seem to qualify as public disclosures").

For example, on January 22, 2007, an article entitled "The Feds Eye Endo" appeared on The Motley Fool investment website and stated that Endo had been forced to disclose that HHS "had begun investigating its sales practices for [Lidoderm]" and that the company had received a subpoena. See Exhibit "E" hereto (article). The article added that the United States was investigating "what Endo knew about physicians' 'non-indicated' use of the drug," which was important because, although Lidoderm was FDA-approved to treat PHN, "at least half of the Lidoderm prescriptions were for other indications." Id. Similar information – that Endo was being investigated by HHS for alleged off-label marketing practices for Lidoderm and had received a subpoena as a result -- also appeared in articles in: (1) the Philadelphia Inquirer (January 18, 2007: "Endo Must Provide Data on Marketing of Pain Patch") (Exhibit "F" hereto); (2) the Pharmaceutical Business Review (January 18, 2007: "Endo Receives Subpoena Over Lidoderm Promotion") (Exhibit "G" hereto); (3) Reuters (January 17, 2007: "Endo Gets US Subpoena Over Pain Patch Promotion") (Exhibit "H" hereto); (4) Medical Marketing and Media (January 23, 2007: "Endo Receives Subpoena on Lidoderm Promotion" (Exhibit "I" hereto); (5) Drugs.com (January 17, 2007: "Endo Pharmaceuticals Receives Subpoena From U.S. Department of Health and Human Services") (Exhibit "J" hereto); and (6) Newsinferno.com (January 18, 2007: "Endo Pharmaceuticals Gets Subpoena From HHS About Lidoderm Patch") (Exhibit "K" hereto). Finally, in its 2007 SEC 10-K filing, Endo revealed that it had received the HHS subpoena in 2007 and that the government was investigating the company's Lidoderm marketing. (Exhibit "C" hereto.)

Assuming that the Court determines that any of the above qualify as a public disclosure under the statute, the second inquiry is whether either of the Weathersby relators or Dr. Dhillon is an "original source." Under Section 3730(e)(4)(B), an original source must have: (1) had both direct and independent knowledge of the information upon which the allegations are based; and (2) voluntarily provided the information to the United States before filing the action. United States ex rel. Paranich v. Sorgnard, 396 F.3d 326, 335 (3rd Cir. 2005). Whether relators' allegations were based not on publicly disclosed allegations but, rather, on the relators' own "direct and independent" knowledge" is a fact-based inquiry. Rockwell Intern. Corp. v. U.S., 549 U.S. 457, 471 (2007). Without this "independent knowledge," as stated in the FCA, the relator will not qualify as an original source.

In the Mistick decision, the Third Circuit explained that "[w]hile it is not necessary for a relator to have all the relevant information in order to qualify as 'independent,'" a relator cannot be said to have "direct and independent knowledge of the information on which [its fraud] allegations are based . . . if the relator has no direct and independent knowledge of the allegedly fraudulent statements." Mistick, 186 F.3d at 389, quoting United States ex rel. Stinson, et al. v. Prudential Ins. Co., 944 F.2d 1149, 1160 (3rd Cir. 1991). See generally United States ex rel. Shumann v. AstraZeneca Pharmaceuticals, LP, 2013 WL 300745, at *7-8 (E.D. Pa. Jan. 24, 2013) ("It is not enough . . . that the relator learn the information via his employment, but he must do so without deriving that information from others"). Upon determining that "independent knowledge" has been established, the Court must then determine whether the information was voluntarily provided to the United States before the action was filed. Like the previous analysis,

this is done through a review of the facts. If a relator cannot qualify as an original source, then the public disclosure bar requires dismissal of his claims.

CONCLUSION

The United States respectfully requests the Court to consider the foregoing analysis and statement of the United States' views when determining the relators' eligibility for a share of the federal settlement proceeds.

Respectfully submitted,

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